

REMARKS

Claims 1-48 are pending and under consideration. With this Amendment, Claims 1, 8, 10, 25, 29, 40, 42 and 43 are being amended and Claim 41 is being cancelled, without prejudice. No claims are being added. Thus, after entry of this Amendment, Claims 1-40 and 42-48 remain pending and under consideration. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail, below.

The Amendments of the Claims

Claim 1 has been amended to focus more clearly on methods of treatment. The amendment is supported by the original claim.

Claim 8, has been amended to correct an obvious error in antecedent basis. Its scope remains unchanged.

Claim 10 has been amended to correct an obvious typographical error which omitted a space between two possible alternatives for substituents R³⁹ and R⁴⁰. Its scope remains unchanged.

Claim 25 has been amended to include dashes after the substituent positions. Its scope remains unchanged.

Claim 29 has been amended to correct an obvious error in antecedent basis. Its scope remains unchanged.

Claims 40, 42 and 43 have been amended to their multiple dependencies, as some of the claims upon which they depended were themselves multiple dependents upon multiple dependent claims. Applicants reserve the right to add properly dependent claims to the instant application upon an indication that amended Claims 40, 42 and 43 recite allowable subject matter.

None of the amendments herein introduce new matter into the instant application. Accordingly, entry thereof is proper and kindly requested.

Provisional Double Patenting Rejections

Claims 1-48 stand *provisionally* rejected under the judicially-created doctrine of obviousness-type double patenting over Claims 1, 9-29, 31-36, 45, 47, 49 and 50 of commonly-owned copending application No. 10/355,543 (the “‘543 application”) and Claims 20-24 and 26-29 of commonly-owned copending application No. 10/858,343 (the “‘343 application”). Applicants traverse the rejections.

Indeed, Applicants do not understand the basis of the rejections. Regarding the rejection based upon the ‘543 application, the Patent Office correctly notes that Claims 1, 9-29, 31-36, 45, 47, 49 and 50 of the ‘543 application are directed to certain 2,4-pyrimidinediamine compounds *per se* and that Claims 1-48 of the instant application are directed to methods of using certain 2,4-pyrimidinediamine compounds, yet contends that instant Claims 1-48 are not patentably distinct from those of the ‘543 application, because the relationship “makes the compounds and compositions of the copending application an obvious variation of the patent application,” Office Action at page 2 (emphasis supplied). This statement is flawed in two respects, making the rejection improper.

First, the issue in the instant case is whether the instant claims are obvious in light of the claims of the copending ‘543 application. Not, as stated in the Office Action, whether the claims of the copending ‘543 application are obvious in light of the instant claims. To the extent the Office believes this is the case, it should provisionally reject the claims in the copending ‘543 application, not the claims of the instant application.

Second, the Office contends that the compounds and compositions of the copending ‘543 application are an obvious variation of *the present application*. As the Patent Office is no doubt aware, issues of obviousness-type double patenting relate to *claims*, i.e., whether the claims of a later-filed application are obvious over the claims of an earlier-filed application or patent (see, e.g., MPEP § 804.B.1). Whether the claims might be obvious over the *disclosure* is simply irrelevant:

When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention

defined in the claim of a patent, *the disclosure of the patent may not be used as prior art.*

General Foods Corp. v. Studiengesellschaft Kohle mbH, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992) (emphasis supplied) (see also MPEP § 804.B.1 at page 800-21, Col. 2).

Thus, since the instant application was filed after the copending '543 application, the relevant inquiry is whether Claims 1-48 of the instant application would have been an obvious variation of Claims 1, 9-29, 31-36, 45, 47, 49 and 50 of the copending '543 application (see, e.g., MPEP § 804.B.1(a)). As specified by the MPEP, the analysis employed in an obviousness-type double patenting determination parallels the guideline for an obviousness rejection under Section 103(a), and should make clear:

- (A) The differences between the inventions defined by the conflicting claims – a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent.

MPEP § 804.B.1 (at page 800-21, Col. 2).

The instant rejection falls far short of the mark. Completely lacking in the rejection is any reasoning whatsoever as to *why* an ordinarily skilled artisan would have found the instantly claimed methods of use obvious in light of the claims of the copending '543 application, which are drawn to compounds *per se*. Accordingly, the rejection is improper and should be withdrawn.

The rejection based upon the copending '343 application is improper for the same reasons, and should likewise be withdrawn. Like the rejection based upon the '543 application, this rejection also appears to be "backwards" in that it focuses on the claims of the copending '343 application instead of the claims of the instant application.

Moreover, it is also noted that the claims of this '343 application are directed to intermediate compounds useful for synthesizing various 2,4-pyrimidinediamine compounds. The Patent Office has provided no reasoning whatsoever as to why an ordinarily skilled artisan

would have found instant Claims 1-48, which are directed to methods of treating autoimmune diseases with certain 2,4-pyrimidinediamine compounds, obvious in view of claims drawn to synthetic intermediate compounds *per se*. Accordingly, the rejection is improper and should be withdrawn for this additional reason.

Rejection Under 35 U.S.C. § 112, ¶ 1

Claims 1-48 stand rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement owing to the recitation of “prevention” in independent Claim 1. Although Applicants do not agree with the propriety of the rejection, in order to expedite prosecution, Applicants have amended independent Claim 1, and hence dependent Claims 1-40 and 42-48, to delete prevention, rendering the rejection moot (it is noted that Claim 41 has been deleted). Accordingly, withdrawal of the rejection of Claims 1-48 under 35 U.S.C. § 112, first paragraph, is requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-48 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,958,935 to Davis et al. (“Davis et al.”). The rejection is moot as applied to cancelled Claim 41 and traversed with respect to amended Claims 1-40 and 42-48.

The basis of the rejection is rooted in the Patent Office’s belief that the Davis et al. reference teaches the same compounds as those recited in the present claims. In particular, the Patent Office contends that the compounds taught at Col. 8, line 59 through Col. 9, line 15 of the Davis et al. reference teaches the same compounds as those recited in the instant Claim 39. The Patent Office is mistaken.

The referenced section of the Davis et al. reference teaches certain 2-pyrimidinediamine and 2,4-pyrimidinediamine compounds. The 2-pyrimidinediamine compounds are irrelevant to the instant analysis. All of the 2,4-pyrimidinediamine compounds bear a 3,4,5-trimethoxyphenyl substituent at the N2 nitrogen atom of the 2,4-pyrimidinediamine ring:

N,N'-bis (3,4,5-trimethoxyphenyl)-2,4-pyrimidinediamine (Col. 8:60-61);
 N4-(3,4-dimethoxyphenyl)-N2-(3,4,5-trimethoxyphenyl)-2,4-pyrimidinediamine
 (Col. 9:1-2);
 N4-[(4-(ethoxycarbonylmethyl)phenyl]-N2-(3,4,5,-trimethoxyphenyl)
 -2,4-pyrimidinediamine (Col. 10:9-10);
 N4-(4-hydroxyphenyl)-N2-(3,4,5-trimethoxyphenyl)-2,4-pyrimidinediamine (Col 10:11-12); and
 N4-[4-(3-aminopropoxy)phenyl]-N2-(3,4,5-trimethoxylphenyl)-2,4-pyrimidinediamine
 (Col. 10: 13-14).

In contrast, none of the compounds recited in Claim 39 include an N2-(3,4,5-trimethoxyphenyl) substituent:

<u>Compound</u>	<u>Example</u>	<u>Name</u>
R921302	7.3.147	N2,N4-Bis(3-aminophenyl)-5-fluoro-2,4-pyrimidinediamine
R926891	7.3.827	N4-(3-Chloro-4-methoxyphenyl)-5-fluoro-N2-[3-[(N-methylamino)carbonylmethyleneoxy]phenyl]-2,4-pyrimidinediamine
R940343	7.3.904	N4-[(2,2-Dimethyl-4H-benzo[1,4]oxazin-3-one)-6-yl]-5-fluoro-N2-[3-(methylaminocarbonylmethyleneoxy)phenyl]-2,4-pyrimidinediamine
R940347	7.3.910	N4-[(2,2-Dimethyl-4H-5-pyrido[1,4]oxazin-3-one)-6-yl]-5-fluoro-N2-[3-(methylaminocarbonylmethyleneoxy)phenyl]-2,4-pyrimidinediamine
R921303	7.3.907	N4-[(2,2-Difluoro-4H-benzo[1,4]oxazin-3-one)-6-yl]-5-fluoro-N2-[3-(methylaminocarbonylmethyleneoxy)phenyl]-2,4-pyrimidinediamine

Indeed, none of the compounds taught in the Davis et al. reference are embraced by formula (I) of instant Claim 1. Proviso (1) specifically excludes certain compounds in which the R² substituent (i.e., the substituent attached to the N2 nitrogen atom of the 2,4-pyrimidinediamine ring) is a 3,4,5-tri(C1-C6) alkoxyphenyl. As mentioned above, all of the compounds taught at Cols. 8-9 of the Davis et al. reference include an N2-(3,4,5-trimethoxyphenyl) substituent at this N2 nitrogen atom (see, e.g., structure Ia of Davis et al. at Col. 8, lines 3-20). With the exception of Examples 113-118 and 133, all of the compounds specifically taught in the Examples section of the Davis et al. reference, whether 2-pyrimidinediamine or 2,4-pyrimidinediamine, also include a 3,4,5-trimethoxyphenyl substituent at the N2 nitrogen atom of the 2-pyrimidinediamine or 2,4-pyrimidinediamine ring. All of these compounds are excluded from Claim 1 by way of proviso (1). The compounds

taught in Example 113-118 and 133 of the Davis et al. reference are excluded from instant Claim 1 by virtue of proviso (4).

Since the Davis et al. reference neither teaches nor suggests compounds recited in instant Claim 1, the Davis et al. reference does not anticipate Claim 1, or Claims 2-40 and 42-48 that depend therefrom. Withdrawal of the rejection of pending Claims 1-40 and 42-48 as being anticipated under 35 U.S.C. §102(b) by Davis et al. is therefore requested.

Conclusion

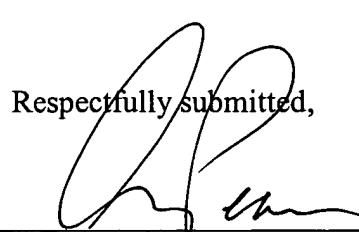
Based on the foregoing, Applicants submit Claims 1-40 and 42-48 are in condition for allowance. If any matters can be resolved by telephone, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

No fees beyond those included with the accompanying papers believed due in connection with this Amendment. However, the Commissioner is authorized to charge any fee that may be required, or credit any overpayment, to Dechert Deposit Account 50-2778 (**Order No. 375462-012US (355218)**).

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Respectfully submitted,


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